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APPLICATION NUMBER	FILING DATE	FIRST NAMED APPLICANT	ATTORNEY DOCKET NO.
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08/737,633 11/15/96 SAMARITANI F P/42-60

18M1/1028

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EXAMINER

FITZGERALD, D

ART UNIT

PAPER NUMBER

1812

2

DATE MAILED: 10/28/97

This is a communication from the examiner in charge of your application.
COMMISSIONER OF PATENTS AND TRADEMARKS

OFFICE ACTION SUMMARY

- ☒ Responsive to communication(s) filed on 01 August 1997
- ☒ This action is FINAL.

- ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 D.C. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire THREE (3) month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

Disposition of Claims

- ☒ Claim(s) 1-10 is/are pending in the application.
- Of the above, claim(s) _____ is/are withdrawn from consideration.
- ☐ Claim(s) _____ is/are allowed.
- ☒ Claim(s) 1-10 is/are rejected.
- ☐ Claim(s) _____ is/are objected to.
- ☐ Claims _____ are subject to restriction or election requirement.

Application Papers

- ☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.
- ☐ The drawing(s) filed on _____ is/are objected to by the Examiner.
- ☐ The proposed drawing correction, filed on _____ is ☐ approved ☐ disapproved.
- ☒ The specification is objected to by the Examiner.
- ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

- ☒ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).
- ☒ All ☐ Some* ☐ None of the CERTIFIED copies of the priority documents have been
- ☐ received.
- ☐ received in Application No. (Series Code/Serial Number) _____.
- ☒ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

*Certified copies not received: _____

- ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

- ☐ Notice of Reference Cited, PTO-892
- ☐ Information Disclosure Statement(s), PTO-1449, Paper No(s) _____
- ☐ Interview Summary, PTO-413
- ☐ Notice of Draftsperson's Patent Drawing Review, PTO-948
- ☐ Notice of Informal Patent Application, PTO-152

1. Applicant's amendment has obviated the rejections under 35 U.S.C. § 102(b) as set forth at ¶¶ 3 and 4 of the Office action mailed 13 May 1997 (Paper No. 5).

Insofar as the rejections of record are maintained below, applicant's arguments filed 4 August 1997 have been fully considered, but they are not persuasive.

5 The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

2. To properly attend to formalities, the examiner notes that this application was filed under the provisions of 35 U.S.C. § 371. The examiner has reviewed and considered the International Search Report (PCT/ISA/210) and the International Preliminary Examination Report (PCT/IPEA/409) prepared during the international stage of this application. Additionally, the
10 references cited in the Search Report, which applicant has cited in an Information Disclosure Statement, have been considered.

3. Pages 1, 3, and 5 of the specification as filed lack sufficient clarity and contrast between the paper and the writing thereon to permit the direct production of readily legible copies
15 by xerographic methods. Substitute pages are therefore required pursuant to 37 C.F.R. § 1.52(a). Such pages should be submitted with an amendment directing their entry into the specification and containing a statement to the effect that they are identical to the corresponding pages of the application as filed.

4. Claims 1-10 are rejected under 35 U.S.C. § 112, second paragraph, as being
20 indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 1-10 are confusing and indefinite because glycine is not a polyol, as recited in amended claim 1.

5. The rejection under 35 U.S.C. § 103(a) of claims 1-10 as unpatentable over
25 Cymbalista '454 as taken in view of Hershenson '605 and Rideout '232 for the reasons set forth at ¶ 6 of Paper No. 5 and below.

Applicant urges that the amendment obviates the rejection because the claims now avoid reading on the examples of the '454 and '605 patents. This argument is not persuasive because the teachings of the references are not limited to what they exemplify; furthermore, "the test of
30 obviousness is not express suggestion of the claimed invention in any or all of the references but

rather what the references taken collectively would suggest to those of ordinary skill in the art presumed to be familiar with them.” *In re Rosselet*, 52 CCPA 1533, ___, 146 USPQ 183, 186 (CCPA 1965); emphasis in original. It remains that it would have been obvious to formulate an IFN- β composition containing mannitol as the sole polyol because both Cymbalista and Hershenson teach that mannitol stabilizes IFN- β , and Cymbalista exemplifies the preparation of a stable formulation comprising only one polyol. It further would have been obvious to formulate such compositions without glycerol and PEG because Cymbalista evidences that such components were not necessary to obtain a stable IFN- β formulation, and Hershenson contains no teachings to the contrary. Finally, applicant has provided no additional evidence which would call such conclusions into question. It therefore remains the determination of the Office that based on the preponderance of the evidence of record, the invention as claimed would have been obvious to one having ordinary skill in the art at the time the invention was made.

6. It is believed that all pertinent arguments have been addressed. No claim is allowed.

7. Applicant's amendment necessitated the new grounds of rejection. Accordingly, **THIS ACTION IS MADE FINAL.** See M.P.E.P. § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 C.F.R. § 1.136(a).

A shortened statutory period for response to this final action is set to expire three months from the date of this action. In the event a first response is filed within two months of the mailing date of this final action and the advisory action is not mailed until after the end of the three-month shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 C.F.R. § 1.136(a) will be calculated from the mailing date of the advisory action. In no event will the statutory period for response expire later than six months from the date of this final action.

8. Any inquiry concerning this communication should be directed to David Fitzgerald, who can be reached by any of the following means:

Telephone (703) 308-3934

Fax

All formal papers (703) 308-4242

Informal communications (703) 308-0294

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Concerning this application
General communications

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PLEASE NOTE THE NEW FAX NUMBER FOR FORMAL PAPERS. ALSO NOTE THE NEW ADDRESS FOR APPLICATION-SPECIFIC E-MAIL AND THE POLICIES DESCRIBED IN THE BOX BELOW.

Inquiries of a general nature should be directed to the Chemical Matrix receptionists at (703) 308-0196.



DAVID L. FITZGERALD
PRIMARY EXAMINER
ART UNIT 1812

27 October 1997

Examiner Fitzgerald is generally available weekdays from 8 a.m. to 4 p.m. (Eastern). If he is not available to take a call, a message may be left on his voicemail. Should attempts to reach him be unsuccessful, the supervisor for Art Unit 1812, Stephen Walsh, may be reached at (703) 308-2957.

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Most official papers and all informal communications may be submitted to the PTO by fax. For specific policies, refer to 37 C.F.R. § 1.6 and the notice published at 1096 O.G. 30.

Communications via **Internet e-mail regarding this application**, other than those under 35 U.S.C. § 132 or those which otherwise require a signature, may be used by applicants and **should be sent to stephen.walsh@uspto.gov**.

All such Internet e-mail communications will be made of record in the application file. PTO employees cannot engage in Internet communications where there exists a possibility that sensitive information could be identified or exchanged unless the record includes a properly signed express waiver of the confidentiality requirements of 35 U.S.C. § 122. This policy is more fully set forth in the Interim Internet Usage Policy published in the PTO's *Official Gazette* on 25 February 1997 at 1195 O.G. 89.